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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,137	01/19/2005	Kenichi Yamashita	2005_0047A	2521
513 7590 08/31/2009 WENDEROTH, LIND & PONACK, L.L.P. 1030 15th Street, N.W., Suite 400 East Washington, DC 20005-1503				
EXAMINER				
POHNERT, STEVEN C				
ART UNIT		PAPER NUMBER		
1634				
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08/31/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/522,137

**Applicant(s)**

YAMASHITA ET AL.

**Examiner**

STEVEN C. POHNERT

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 October 2008.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 4 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1 and 4 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 15 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/22/2008 has been entered.

***Claim status and Formal matters***

This action is in response to amendments filed 10/30/2008 in view of the RCE filed 7/22/2008.

This is a first action merits following RCE. The office action of 10/15/2008 has been withdrawn in its entirety as the request for the RCE included a suspension of action.

Claims 1 and 4 are pending.

All previous rejections are withdrawn in view of the amendment to require the simultaneous passing of a specimen solution and a separate solution containing a fluorescent probe into a microflow channel, which is not taught by Wolinsky.

***Priority***

The instant application was filed on 1/19/2005 and is a National Stage entry of PCT/JP03/09142 filed 7/18/2003. The application claims priority to Japanese application 2002-211462 filed July 19, 2002.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Weigl et al (WO00/72020 Published 11/30/200) (IDS 1/19/2005)..

Weigl teaches, "This invention also provides methods for detecting the presence of at least first and second analyte particles in a first fluid comprising: providing a second fluid comprising first and second binding particles for said first and second analyte particles, respectively; flowing said first and second fluids in adjacent laminar flow in a laminar flow channel ; allowing said first analyte particles to diffuse into said second fluid and bind with said first binding particles to form first complexes; and allowing said second analyte particles to diffuse into said second fluid and bind with said second binding particles to form second complexes; and detecting the presence of said first and second complexes. The first and second complexes may have detectably different diffusion coefficients and/or may form detectably different diffusion profiles, e. g. because the diffusion front for each is in a different position, or because the first and second complexes are differently labeled. The first and second complexes may or may not be labeled with detectably different labels. If detectably different labels are not used, different diffusion coefficients of the two complexes may enable them to be drawn out of the laminar flow channel at different points, in separate outlet streams, each comprising either the faster-diffusing complexes or mixtures of complexes. Diffusion separators

connected in series may continue to purify and refine the separator products. The various complexes may then be detected in the separate streams by means known to the art " (bottom page 3-page 4).

Weigl teaches, "Slowing of the diffusion front may be observed or detected; or the position of the diffusion front after a predetermined time from when the particles begin diffusing may be observed or otherwise detected and compared with a similar calibration or control system or systems containing known amounts of analyte particles, e. g. from 0 to any typical concentration." (page 3, lines 20-24).

Weigl teaches, "Computer processor means may be used to determine the presence or concentration of the analyte particles from the detected diffusion profile. The processor may be programmed to compare the diffusion profile with diffusion profiles taken using varying known concentrations of analyte, e. g., calibration curves or diffusion profiles in reference streams or to calculate analyte concentrations using algorithms described below. "(page 13 bottom- top page 14).

Weigl teaches detection by fluorescence (page 13).

Weigl thus teaches a method of simultaneously passing a solution containing specimen molecules and a separate solution containing probe molecules capable of forming a complex with the specimen into a flow channel such that laminar flows occur and differences in the degree of diffusion are determined by the affinity of faster flowing complexes by fluorescence and comparing the results to a calibration curve.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over by Weigl et al (WO00/72020 Published 11/30/2000) (IDS 1/19/2005) in view of Weigl et al (US Patent 5, 972,710 issued Oct 26, 1999)

Weigl et al (WO00/72020 Published 11/30/200) will be referred to in this rejection as Weigl (A).

Weigl et al (US Patent 5, 972,710 issued Oct 26, 1999) will be referred to as Weigl (B).

Weigl (A) teaches, "This invention also provides methods for detecting the presence of at least first and second analyte particles in a first fluid comprising: providing a second fluid comprising first and second binding particles for said first and second analyte particles, respectively; flowing said first and second fluids in adjacent laminar flow in a laminar flow channel ; allowing said first analyte particles to diffuse into said second fluid and bind with said first binding particles to form first complexes; and allowing said second analyte particles to diffuse into said second fluid and bind with said second binding particles to form second complexes; and detecting the presence of said first and second complexes. The first and second complexes may have detectably different diffusion coefficients and/or may form detectably different diffusion profiles, e.

g. because the diffusion front for each is in a different position, or because the first and second complexes are differently labeled. The first and second complexes may or may not be labeled with detectably different labels. If detectably different labels are not used, different diffusion coefficients of the two complexes may enable them to be drawn out of the laminar flow channel at different points, in separate outlet streams, each comprising either the faster-diffusing complexes or mixtures of complexes. Diffusion separators connected in series may continue to purify and refine the separator products. The various complexes may then be detected in the separate streams by means known to the art " (bottom page 3-page 4).

Weigel (A) teaches, "Slowing of the diffusion front may be observed or detected; or the position of the diffusion front after a predetermined time from when the particles begin diffusing may be observed or otherwise detected and compared with a similar calibration or control system or systems containing known amounts of analyte particles, e. g. from 0 to any typical concentration." (page 3, lines 20-24).

Weigel (A) teaches, "Computer processor means may be used to determine the presence or concentration of the analyte particles from the detected diffusion profile. The processor may be programmed to compare the diffusion profile with diffusion profiles taken using varying known concentrations of analyte, e. g., calibration curves or diffusion profiles in reference streams or to calculate analyte concentrations using algorithms described below. " (page 13 bottom- top page 14).

Weigel (A) teaches detection by fluorescence (page 13).

Weigel (A) thus teaches a method of simultaneously passing a solution containing specimen molecules and a separate solution containing probe molecules capable of forming a complex with the specimen into a flow channel such that laminar flows occur and differences in the degree of diffusion are determined by the affinity of faster flowing complexes by fluorescence and comparing the results to a calibration curve.

Weigel (A) does not teach the use of a DNA fragment.

However, Weigl (B) teaches a similar microchannel system that can be used to detect DNA sequences or antibody and antigens (bottom column 3-top of column 4).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to detect DNA sequences in the method of Weigl (A) as taught by Weigl (B). The artisan would be motivated to detect DNA instead of protein/antigen because it allows for direct detection of genetic materiality and is not dependent on transcription or post-transcriptional processing, thus allowing direct genetic characterization of the sample. The artisan would have a reasonable expectation of success as Weigl (B) suggests that microchannel can be used for detection of protein or DNA binding.

### **Summary**

No claims are allowed.

### **Conclusions**



Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEVEN C. POHNERT whose telephone number is (571)272-3803. The examiner can normally be reached on Monday-Friday 6:30-4:00, every second Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Steven C Pohnert/  
Examiner, Art Unit 1634

Steven Pohnert